510(k) Summary
for The OrthoPro Ankle Trauma System
In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for The OrthoPro Ankle Trauma system

FEB 2 8 2013

Date Prepared: September 21, 2012
Date Updated: January 28, 2013

1. Submitter:
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Salt Lake City, UT 84106

Contact Person:
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Telephone: 801-746-0208 ext 109

2. Trade Name: **The OrthoPro Ankle Trauma System**
Common Name: **bone plate**
Classification Name: **Single/Multiple Component Metallic Bone Fixation Appliances and Accessories**
21 CFR § 888.3030
HRS
Class II

3. Predicate or legally market devices which are substantially equivalent:
- **LCP One-Third Tubular Plate – K011335 (Synthes)**
- **T-3.5mm LCP T-Plate – K000684 (Synthes)**
- **LCP Distal Tibia Plate – K013248 (Synthes)**

4. Description of the device:
The OrthoPro Ankle Trauma system is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation of long bones and bone fragments. The plates include straight, right, and left configurations. The system also includes bone screws. Manual surgical instruments are supplies with the system to facilitate implantation.

Materials:
Titanium alloy (Ti 6Al 4V ELI) per ASTM F136

5. Indications for Use:
The OrthoPro Ankle Trauma system is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone, The OrthoPro Ankle Trauma system is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia and other small bones as a part of the system.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:
The OrthoPro Ankle Trauma system is substantially equivalent to the Synthes devices: One-Third Tubular Plate, T-3.5mm LCP T-Plate, LCP Distal Tibia Plate in terms of intended use, design, and

materials used. The table below compares the features and characteristics of Ankle Trauma System to these predicate devices.

Device Name/Items	**OrthoPro Ankle Trauma System**	**Synthes LCP One-Third Tubular Plate**	**Synthes T-3.5mm LCP T-Plate**	**Synthes LCP Distal Tibia Plate**
Sponsor	OrthoPro LLC	Synthes (USA)	Synthes (USA)	Synthes (USA)
Device Classification Name	Single/Multiple component metallic fixation appliances and accessories	Single/Multiple component metallic fixation appliances and accessories	Single/Multiple component metallic fixation appliances and accessories	Single/Multiple component metallic fixation appliances and accessories
Product code	HRS	HRS	HRS	HRS
Regulation #	888.3030	888.3030	888.3030	888.3030
Classification	Class II	Class II	Class II	Class II
510(k) Number	K122936	K011335	K000684	K013248
Indications for Use	The OrthoPro Ankle Trauma system is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone, The OrthoPro Ankle Trauma system is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia and other small bones as a part of the system.	Synthes Dynamic Compression Locking Plate System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone as part of the Synthes Small Fragment DCL System	Fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula particularly in osteopenic bone.	The Synthes Locking Compression Plate (LCP) is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone, The Synthes LCP Distal Tibia Plates are intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia and other small bones as a part of the system.
Material	Titanium	Titanium and stainless steel	Titanium and stainless steel	Titanium and stainless steel
Configuration	Straight, Cloverleaf	Straight	Straight, T, cloverleaf, T oblique angle, curved	Cloverleaf
Profile	Scalloped	Straight	Staight, Scalloped	Straight
Screws	Locking and Non-locking	Locking and Non-locking	Locking and Non-locking	Locking and Non-locking
Sterility	Non-sterile	Sterile/Non-sterile	Sterile/Non-sterile	Sterile/Non-sterile

7. Nonclinical Test Summary:

   The worse case plate from the Ankle Trauma System was tested against the predicate device using the standard ASTM F382-99 Standard Specification and Test Methods for Metallic Bone Plates. The OrthoPro plate was found to be substantially equivalent to the predicate device. The screws from the Ankle trauma system were tested against the predicate device using the standard ASTM F543-07 Standard Specification and Test Methods for Metallic Bone Screws. The screws from the Ankle Trauma System were found to be substantially equivalent to the predicate device.

8. Clinical Test Summary:

   No clinical studies were performed.

9. Conclusions Nonclinical and Clinical:

The OrthoPro Ankle Trauma System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function; in most cases with respect to device function performed with superiority.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

OrthoPro, LLC
% Mr. Brock Johnson
Vice President Operations
3450 Highland Drive
Salt Lake City, Utah 84106

Re: K122936
Trade/Device Name: The OrthoPro Ankle Trauma System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 28, 2013
Received: February 8, 2013

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin F. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number (if known): K122936

Device Name: The OrthoPro Ankle Trauma system

Indications for Use:

The OrthoPro Ankle Trauma system is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly in osteopenic bone, The OrthoPro Ankle Trauma system is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia and other small bones as a part of the system.

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices